

ENVIRONMENTAL ASSESSMENT

1. **DECEMBER 8, 2004**
2. **ECOLAB INC.**
3. **ECOLAB CENTER**
370 Wabasha Street
St. Paul, MN, 55102-1390
4. **DESCRIPTION OF THE PROPOSED ACTION**

a. Requested Action

It is proposed that Polybetaine Polysiloxane Copolymer (PPC) be approved for use as an indirect food additive through the premanufacture process utilizing the FDA Form 3480 "Notification for New Use of a Food Contact Substance." PPC is proposed for use as a processing aid in rinse-aid products at concentrations up to 2.14 ppm (25% above the maximum current "at-use" concentration of 1.71 ppm) in the final rinse water of commercial dishwashing machines.

which is a solution of PPC in water and propylene glycol, is manufactured by Goldschmidt Chemical Corporation, a wholly-owned subsidiary of Degussa Corporation. The industrial site is bordered by and other industrial or undeveloped properties within the city of The local wastewater treatment plant (POTW) is located less than 1 mile from the facility and certain permitted wastes are discharged to this POTW. Solid process waste is disposed of by contracts with RCRA Part B permitted facilities. Some airborne emissions from manufacture of consist of low molecular volatile compounds that are components of materials used in the process. The facility has appropriate control technology so that the plant operates within its DEQ air permits.

b. Need for Action

The purpose of PPC in these products is to improve sheeting of water, particularly from the surfaces of plastic substrates. Because of the chemistry of plastics, water tends to remain longer on the surface of plastics than on other substrates, such as ceramics or glass. Without PPC, the water remains on the plastic surface longer, resulting in increased spotting and dampness during storage.

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c. Location of Use/Disposal

PPC is added to rinse-aid products at various Ecolab sites in the United States (see table on page 5). These sites are secure production facilities situated on the edge or within a few miles of small/medium towns in largely industrial areas. The types of environments present at and adjacent to these locations include water sources. There will be no solid by-products or airborne discharges from the production of rinse-aid products.

Regarding disposal of the rinse-aid products containing PPC, these products will be used in patterns corresponding to national population density and will be widely distributed across the country. Consequently, disposal will occur nationwide, with liquid wastes from use of these products in commercial dishwashing machines ultimately being discharged to local POTWs, which are regulated under local, state, and federal agencies. Solid byproducts, consisting of packaging only, will ultimately be deposited in landfills, incinerated, or recycled (where possible). Environments potentially affected by disposal or discharge of PPC from rinse-aid products will be watersheds or groundwater receiving leachate from land disposal sites or POTWs and areas subject to air emissions from landfills and incineration sites. There will be no direct airborne discharges from use of rinse-aid products.

5. IDENTIFICATION OF THE SUBSTANCE THAT IS THE SUBJECT OF THE PROPOSED ACTION

a. Chemical Name

Polybetaine Polysiloxane Copolymer

b. Common Names

Dimethicone propyl PG-betaine; cetyl dimethicone polyol; propyl PG-betaine dimethicone polyol; PPC

c. Commercial Name

d. CAS Registry Number

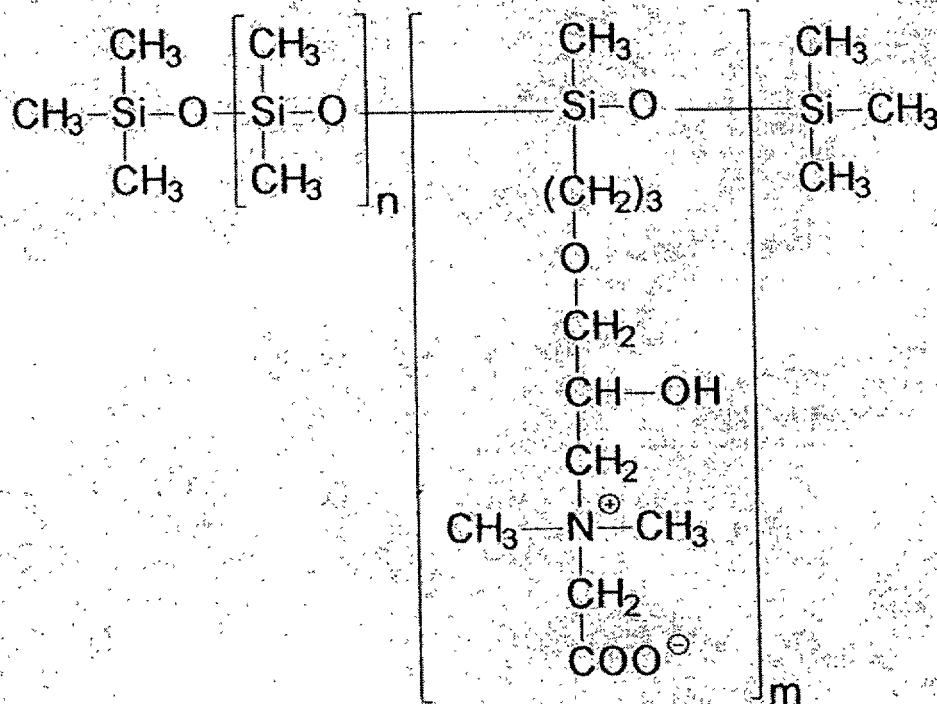
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e. Empirical Formula

$C_{(6+2n+11m)}H_{(18+6n+23m)}Si_{(2+n+m)}O_{(1+n+5m)}$

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f. **Structural Formula**



g. **Properties**

For	
Property	Value
Amounts (% w/w)	
PPC (FCS)	
Propylene glycol	
Water	
Appearance	Amber liquid
Color (Gardner)	4 maximum
pH	5-7
Specific gravity at 25°C	1.07 – 1.09
Viscosity at 25°C	85 – 125 mPas (=85-125 cps)
Specific solubility (10% at 25°C):	
Water	Soluble/turbid
Isopropanol	Soluble
Propylene glycol	Soluble

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6. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

a. Introduction of Substances into the Environment as a Result of Manufacture

(a solution of PPC) is manufactured in by Goldschmidt Chemical Corporation, with total annual production of metric tons (). This amount is for all industrial and commercial uses, not just for the production of rinse-aids. Using a median value of approximately would be reasonable to determine relative amounts used in rinse-aid products. Thus, the use of for rinse-aid products (estimated to be annually) is approximately 2% of total production.

Goldschmidt is responsible for all effluent, solid, and airborne discharges from this facility, and this facility is currently in compliance with emissions requirements. Product loss during manufacture is minimal and either is recycled or is eventually discharged to the local POTW. The General Wastewater Permit for this facility is The State Air Permit is registration number There are no solid wastes from production of

To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of the FCS.

b. Introduction of Substances into the Environment as a Result of Use

The FCS is completely incorporated into rinse-aid products and functions in the finished rinse aids, and essentially all of it is expected to remain with the rinse-aid products throughout their use. As such, little or no substances are expected to be introduced into the environment from the use of the FCS in the manufacture of rinse-aid products.

Annually, approximately of (as a PPC solution) are used in the production of rinse-aid products. PPC is added to these products at various Ecolab sites in the United States (see table on the next page). Ecolab is responsible for all effluent, solid, and airborne discharges from these secure facilities and these facilities are currently in compliance with emissions requirements. Liquid production wastes are regulated under local, state, and federal permit numbers (see the table on the next page). There will be no solid by-products or airborne discharges from production of rinse-aid products.

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Location	Industrial Wastewater Discharge Permits
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These Ecolab facilities produce at least 21 rinse-aid products, of which is only added to 10 products. Of 1 produced in the U.S.), approximately are purchased by Ecolab, of which approximately are used in rinse aids. In addition, PPC is used extensively as a component of personal care products. Consequently, the use of PPC in the production of rinse aids results in minimal or no overall increases of environmental emissions from the Ecolab facilities and also results in no appreciable environmental impact when compared to the use of PPC in all other industries.

c. Introduction of Substances into the Environment as a Result of Disposal

This action involves PPC (the active component in), which is a component of rinse-aid products. PPC will be present at a maximum "at-use" concentration of 2.14 ppm (0.000214 %) by weight in the final rinse water from the use of rinse-aids in commercial dishwashing machines. These machines would likely be used in the commercial establishments, such as restaurants, bars, cafeterias, child and adult day care centers, residential dining facilities and medical institutions. The principal route of environmental introduction of PPC follows from the disposal of liquid wastes through the sewage system into waterways. This disposal route is governed by the EPA's regulations in 40 CFR Subchapter D and/or O and local government wastewater regulations.

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Calculation of the expected introduction concentration (EIC) in ppb is as follows (from FDA, 1998):

A x B x C x D, where

A =

B =

C =

D =

$$= 6.15 \times 10^{-2} \text{ ug/L/day}$$

Thus, the EIC for PPC is 6.15×10^{-2} ppb.

Based on the low levels of PPC in rinse-aid products, the subsequent dilution in the rinse water, and the total amount of PPC produced in the US for other commercial uses, the introduction of this substance from the use in rinse-aid products into local waterways is not environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will threaten a violation of the EPA's regulations governing wastewater or have any other adverse environmental effect.

7. FATE OF THE EMITTED SUBSTANCE IN THE ENVIRONMENT

No published ecotoxicity or environmental fate studies are available that utilize PPC; however, biodegradation would be expected because the monomeric units (betaine and siloxane) are biodegradable.

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The expected environmental concentration (EEC) is the concentration of the active moiety that organisms would be exposed to in the environment after consideration of, for example, spatial or temporal concentration or depletion factors such as dilution, degradation, sorption and/or bioaccumulation (FDA, 1998). Based on dilution factors for POTWs available from the EPA, applying a dilution factor of 10 to the EIC to estimate the EEC is normally appropriate (FDA, 1998). As a consequence, with an EIC of 6.15×10^{-2} ppb, the EEC of PPC is estimated to be 6.15×10^{-3} ppb. Thus, the introduction of this substance from the use of rinse-aid products into local waterways does not appear to be environmentally significant.

One of the copolymers of PPC, betaine, $(\text{CH}_3)_3\text{N}^+\text{CH}_2\text{COO}^-$ (CAS No. 107-43-7), occurs extensively in nature, usually as a result of the metabolism of other biochemicals. Metabolic precursors to betaine are choline, serine, acetylcholine, and lecithin, which are found extensively in plants and animals (Devlin, 1993). Consequently, amounts of betaine in the environment from naturally-occurring processes far exceed amounts that would be introduced into the environment from use of rinse-aid products containing PPC. The levels of PPC in rinse water are a maximum 2.14 ppm and 4-7 moles of betaine are used for every mole of PPC. Consequently, the amount

of betaine in dishwashing rinse water after use of rinse aids containing PPC is a maximum 0.71 ppm.⁽¹⁾ After dilution and bacterial biodegradation in municipal sewage systems, amounts of betaine introduced into the environment from the use in rinse-aid products will be minimal. Thus, the introduction of this substance into local waterways from the use of rinse-aid products does not appear to be environmentally significant.

The second copolymer of PPC is an organosilane. Organosilanes degrade in a variety of soils or on common clay minerals, ultimately to carbon dioxide. These compounds are removed from waste water either by adsorption onto sludge in waste treatment facilities, adsorbing to suspended matter in the effluent or partitioning from the effluent into soil, because they have low water solubility and a high adsorption coefficient for organic matter (Fendinger *et al.*, 1997; Stevens *et al.*, 2001; Graiver *et al.*, 2003). In one study (Fendinger *et al.*, 1997), numerous waste treatment facilities were monitored for the presence of dimethylsiloxane (PDMS). Wastewater treatment removed more than 94% of PDMS, which resulted in effluent concentrations of less than the analytical detection limit of 5 ug/L. In addition, Fendinger and associates (1997) were unable to detect PDMS in surface water but found this compound in dry sediment at levels of up to 6 ppm and in soils amended with sludge at levels of 3.7 ppm. Soils or minerals within the soils catalyze the hydrolysis of the carbon-silicon bond (Graiver *et al.*, 2003). This hydrolysis is random and can quickly reduce the polymer size. The rate of depolymerization is dependent upon soil types, pH, amounts of organic matter, temperature, and the moisture content of the soil. Complete degradation occurs from 1 week (dry soil in the laboratory) to up to 1 year (continuously wet soil) (Carpenter *et al.*, 1995; Lehmann *et al.*, 2000). The predominant chemical produced from this depolymerization is dimethylsilanediol (Lehmann *et al.*, 2000, Graiver *et al.*, 2003). Dimethylsilanediol does not leach downward in soil (Lehmann *et al.*, 2000) but can either biodegrade in soil to carbon dioxide (Lehmann *et al.*, 1998) or volatilize with other low molecular weight oligomers (<400 daltons) into the upper atmosphere. In dry sandy soils, dimethylsilanediol will predominantly volatilize, whereas in damp, dense soils, biodegradation will be the main degradation pathway (Stevens, 1998). Two microorganisms, a fungus, *Fusarium oxysporum* and a bacterium, *Arthrobacter* species were shown to metabolize dimethylsilanediol in liquid cultures to silicic acid (Stevens, 1998). In the upper atmosphere these volatiles are degraded by OH radicals (Graiver *et al.*, 2003). Graiver and associates (2003) found that volatile organosilanes have a negative effect on the formation of low-level ozone. In fact, the U.S. EPA excluded organosilanes and other organosilicons from regulation concerning restriction of volatile organic compounds in the atmosphere. Studies also examined the effects organosilanes have on organisms in the environment. In studies examined by Graiver *et al.* (2003), terrestrial and aquatic plants and microorganisms, and earthworms were unaffected by the presence of organosilanes. In the field study performed by Lehmann and associates (2000),

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(1) Betaine molecular weight (MW) is 117 daltons, PPC average MW is 2500, and a maximum 7 moles of betaine are incorporated in each mole of PPC. Thus, 33% by weight of PPC is betaine ($819/2500 = 0.33$). PPC is a maximum 2.14 ppm in rinse water, which means that 0.71 ppm is the betaine moiety.

ants and plants located on the test plots were unaffected by the presence of organosilanes. The potential for bioaccumulation of organosilanes is minimal for polymers that have a high molecular weight (represented by a viscosity greater than 10 cSt; PPC has a viscosity of 26-51 cSt), although they have a high *n*-octanol/water partition coefficient (Stevens *et al.*, 2001). Studies in guppies and bullhead catfish showed that bioaccumulation of organosilanes does not occur when the molecular weight is greater than 600-1000 daltons ((Stevens *et al.*, 2001). Studies utilizing phyto- and zoo-plankton, crustaceans, and annelid worms exposed to organosilanes and then fed to fish, crabs, or molluscs resulted in no biomagnification of the organosilanes in the aquatic food chains tested. Thus, the introduction of siloxanes into local waterways from the use of rinse-aid products does not appear to be environmentally significant.

Based on the low levels of PPC in rinse-aid products, the subsequent dilution in the rinse water, the total amount of PPC produced in the US for other commercial uses, the widespread presence of one of the monomers (betaine) in biological systems, and the biodegradation of siloxanes, the introduction of this substance from the use in rinse-aid products into local waterways is not environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will have any adverse environmental effect.

8. ENVIRONMENTAL EFFECTS OF THE RELEASED SUBSTANCE

Rinse-aid products will be manufactured at various facilities around the country and their use and disposal will also be widespread throughout the country. Also, only approximately 2% of the total US production of PPC will be used in rinse-aid products. Consequently, the impact of PPC from use in rinse aids on ecological systems at any one site will be minimal or nonexistent.

9. USE OF RESOURCES AND ENERGY

Resources and energy utilization to produce or dispose of either PPC or rinse-aid products containing PPC are not expected to be affected by the action. Overall US production of PPC is expected to remain essentially unchanged as a consequence of this action because the market share of PPC that is utilized in rinse aid products is only a small fraction of total production volumes.

Effects upon endangered or threatened species and upon property listed in or eligible for listing in the National Register of Historical Places are not expected as a result of the action.

10. MITIGATION MEASURES

Measures to avoid or mitigate potential adverse environmental impacts were not considered because no potential adverse effects have been identified.

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11. ALTERNATIVES TO THE PROPOSED ACTION

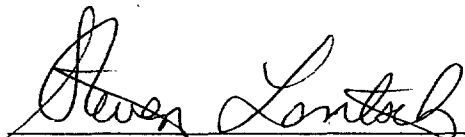
Alternatives to the proposed action were not considered because no potential adverse effects have been identified.

12. LIST OF PREPARERS

Susan D. Phillips, Senior Associate Scientist at ENVIRON International Corporation. M.S. in Pharmacology and Toxicology. Consultant in chemical, toxicological, and pharmacological sciences.

13. CERTIFICATION

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of Ecolab Inc.



Signature of Responsible Official

Dec. 3, 2004

Date

Steven Elentsch Senior Corporate Scientist
Name and Title of Responsible Official (Printed)

14. REFERENCES

Copies of these references (unless otherwise noted) are in FAMF No. 719.

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United States Food and Drug Administration (FDA). 1998. Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications. CMC 6, Revision 1 (a copy is not attached and is not in FAMF No. 719).

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